

REMARKS

Claim 35 has been amended to include the limitations of claim 36 and claim 36 has been canceled. It is noted that although claim 36 was withdrawn from consideration as reading on a non-elected species, such withdrawal of claim 36 was not proper. Claim 36 depended on claim 35 and did not exclude the elected species from its scope as can be seen by the amendments to claim 35.

Claims 35 and 37 are rejected under 35 U.S.C. 112, second paragraph, for being indefinite.

Oath or Declaration

The Examiner notes that PCT/JP98/00351 is identified under "PRIOR FOREIGN APPLICATION(S)" in the declaration filed February 26, 2004, without checking a box (YES or NO) for "PRIORITY CLAIMED UNDER 35 U.S.C. §119".

According to 37 C.F.R. 1.63, a declaration must identify all prior foreign applications, unless such information is provided in an application data sheet, and identify the application to which it is directed, for example, by listing the international application number. If required, applicant will file a Supplemental Application Data Sheet with the response in order to comply with all formal requirements. However, it is noted that the USPTO

records correctly identify the continuity and foreign priority information of the present application.

Claim Rejections - 35 U.S.C. § 112

Claims 35 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention and under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The position of the Office is that the specification does not describe or support a method of prophylaxis and/or therapy of a cancer comprising administering a vaccine prepared by treating cells of said cancer with a compound of the Formula 3-a or prepared from a vaccine precursor prepared by treating the cells of said cancer with a compound of the Formula 3-a. The Office notes that the specification only shows that "Yoshixol" (i.e. the compound of claim 35 wherein all of R_3 , R_4 , R_5 , and R_6 are hydrogen) inhibits growth of a cancer in and/or improves survival time of mice having cancer by administering a composition which comprises sediment of extinct cells of said cancer prepared by treating said cells of cancer with Yoshixol, wherein the cancer is leukemia or melanoma (see pages 40-42). According to the Office, the composition is either administered in animals (mice) that already have cancer to

show increase in survival time or administered to mice implanted with cancer cells to show improvement in the inhibition of cancer growth. The Office further notes that no derivatives of Yoshixol are suggested or used in any experiment to show any effect with regard to cancer growth or survival time and that there is no clear description in the specification about what compound(s) in the composition is responsible for improving the survival time or cancer growth. Finally, the Office notes that the experiment in the application is restricted to rodents and no experiment was done in mammals. The Office states that in view of the limited experiment using rodents, an improvement in survival rate or cancer growth cannot be generalized to all animals.

Regarding indefiniteness under the second paragraph of 35 U.S.C. § 112, the Examiner states that it is unclear in claim 35 what compounds are intended to encompass by the term "vaccine precursor".

Reconsideration of these rejections is respectfully requested for the reasons explained below which will show that the rejections are not proper and should be removed.

1. Rejection under 35 U.S.C. § 112, second paragraph

(1) Indefiniteness of the term "vaccine precursor"

The term "vaccine precursor" means, as it is written, the precursor of a vaccine; that is, a substance which becomes a mature vaccine through some process such as purification, modification and the like. The term "vaccine precursor" has been commonly used in the field relating to the present invention as shown in references listed below. Therefore, the meaning of "vaccine precursor" is clear, and it is believed that this rejection is improper.

D1: Greenberg et al., US Patent No. 4,571,385

D2: R.G. Breeze, Rev. sci. tech. Off. int. Epiz., 2006, 25(1), p.271-292 (in particular, p.277, right column, lines 14-15)

D3: Drew Endy, Nature, vol. 438(24), November 2005, p.449-453 (in particular, p.452, right column, 5th paragraph, line 14)

D4: Sloane et al., US Patent No. 3,493,651 (in particular, column 2, lines 9-11).

2. Rejection under 35 U.S.C. 112, first paragraph

(1) "vaccine precursor"

As described above, the term "vaccine precursor" is commonly used in the field relating to the present invention. Those skilled in the art can understand, from a reading of the present specification in light of the knowledge in the art, what the vaccine precursor in the present invention is and how the vaccine is prepared from the precursor. Concretely, examples of the

vaccine precursor of the present invention include the mixture of Yoshixol and cancer cell culture, and that such vaccine precursor is subjected to purification (washing and filtration) to obtain the vaccine.

(2) "prophylaxis"

(i) It seems that the Office does not correctly understand the meaning of the term "vaccine". As shown in D5 (an excerpt of the home page of National Cancer Institute, "Cancer V a c c i n e F a c t S h e e t", <http://www.cancer.gov/cancertopics/factsheet/cancervaccine>), "cancer vaccines are intended either to treat existing cancers (therapeutic vaccines) or to prevent the development of cancer (prophylactic vaccines)". The vaccine used in the present invention is a cancer vaccine and, therefore, is not restricted to a prophylactic vaccine.

(ii) The Office states that "the composition is either administered in an animal (mice) that already have cancer to show increase in survival time ...". This understanding is wrong. In Examples of the present specification, the composition prepared from Yoshixol-treated leukemia cells was first administered to mice, and then leukemia cells were implanted to the mice. This Example indicates that mice to which the composition (vaccine) was

previously administered are more resistant to cancer than control mice, i.e., a prophylactic effect is also demonstrated in Examples of the present specification.

(3) The effect of the compounds other than Yoshixol

By the above-described amendment, the scope of the compound represented by Formula 3-a is greatly restricted. Further, submitted herewith is a declaration under 37 C.F.R. § 1.132 which presents experimental data in order to show that the prophylactic and/or therapeutic effect is exhibited by the compounds of Formula 3-a recited in the amended claim 35 (other than "Yoshixol").

According to these data, one of the compounds represented by Formula 3-a, 4,4-dimethyl-2-methylene-3,4-dihydronaphthalen-1-one (Yoshixol-7001), has a superior effect to prevent and/or treat cancer similar to that of Yoshixol. Applicant submits that these data using a polycyclic compound Yoshixol-7001 demonstrate the prophylactic and/or therapeutic effect of the compounds of Formula 3-a recited in the amended claim 35.

(4) Regarding the lack of experimental data in mammals

The Office asserts that the Examples of the present specification are restricted to rodents and thus the effect of the present invention cannot be generalized to all animals. However, this assertion is unsupported and is otherwise improper. In the

medical field, numerous patent applications directed to various animals including mammals have been granted without specific data using mammals. Some of such cases are attached hereto (D6-D8, US patent publications). D6 recites "a subject" in its claims, although the experimental data are restricted to mice. D7 recites "a patient" in its claims, although the experimental data are restricted to rats. D8 recites "a subject" in its claims, although the experimental data are restricted to rat cells and mice.

D6: US 6,803,366 B2

D7: US 7,119,076 B2

D8: US 7,226,935 B2

Removal of the rejections under 35 U.S.C. § 112, first and second paragraphs, and a notice of allowability are believed to be in order and are respectfully requested.

The foregoing is believed to be a complete and proper response to the Office Action dated October 19, 2007, and is believed to place this application in condition for allowance. If, however, minor issues remain that can be resolved by means of a telephone interview, the Examiner is respectfully requested to contact the undersigned attorney at the telephone number indicated below.

In the event that this paper is not considered to be timely filed, applicant hereby petitions for an appropriate extension of

PATENT APPLN. NO. 10/786,369
SUBMISSION UNDER 37 C.F.R. § 1.114

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time. The fee for any such extension may be charged to our Deposit Account No. 111833.

In the event any additional fees are required, please also charge our Deposit Account No. 111833.

Respectfully submitted,
KUBOVCIK & KUBOVCIK

A handwritten signature in black ink, appearing to be 'R. Kubovcik', written over a horizontal line.

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Attachments: 8 Reference Documents
Declaration under 37 C.F.R. §1.132 of Shozo KOYAMA